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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,323	02/06/2006	Fabrizio Alessandro Maspero	0076117-000003	1293

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EXAMINER

GHERBI, SUZETTE JAIME J

ART UNIT	PAPER NUMBER
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3738

NOTIFICATION DATE	DELIVERY MODE
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07/24/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No. 10/540,323	Applicant(s) MASPERO ET AL.	
	Examiner SUZETTE J-J GHERBI	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-81 is/are pending in the application.
- 4a) Of the above claim(s) 64-70,80 and 81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-41,46-49,51,53-55,57,59,60,62,63,71-73,75,76 and 78 is/are rejected.
- 7) ☒ Claim(s) 42-45,50,52,56,58,61,74,77 and 79 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/15/09</u> . | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Applicant's election with traverse of **Group I claims 36-63 and 71-79** in the reply filed on 3/26/09 is acknowledged. The traversal is on the ground(s) that there is no undue burden on the examiner. This is not found persuasive because the inventions have acquired a separate status in the art in view of the different classification and require a different field of search i.e. different classes and subclass searching. Claims 64-70 and 80-81 have been withdrawn. The requirement is still deemed proper and is therefore made **FINAL**.

Response to Arguments

Applicant's arguments filed 3/4/09 with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 78 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 78 recites the limitation "void spaces". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 36-39, 41, 46-49, 54-57, 59, 60, 62-63 are rejected under 35 U.S.C. 102(e) as being anticipated by Slivka et al. 6,783,712. Sivka et al. discloses the invention as claimed comprising:

a biocompatible implant for the treatment of defects in a living organism such as bone defects or tooth extraction wounds, comprising at least one zone of impermeability to soft tissue and/or epithelial cells in-growth, wherein said implant is comprised of an open porous scaffold (2:5, 8-10, 42 describes types of pores and 3:51-67 for pore size

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distribution) and a membrane (*see 9:25-35 which states a solid film may be used which is biodegradable film covering an articulating surface of the implant*) covering at least a part of said scaffold and being sealed to it such that said scaffold and said membrane form a single piece of matter that is resorbable by an organism, wherein at least a portion of the open porous scaffold allows an in-growth of regenerating bone tissue (*see 3:31-39 for biodegradable polymers which are synthetic*); and pore ranges (*se 4:5-8*).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-41, 48, 51, 62-63, 71-73, 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Evans et al.** 7,156,880 in view of **Li et al. 6,054,142**. Evans et al. discloses a biocompatible implant scaffold for the treatment of defects such as bone or tooth wounds (*see table 8 for a listing of tissues and procedures treated by the implant of Evans*); with a porous structure for in-growth (*see 19:64-67; 20:1-3; 39-54*); wherein the implant is a composite matrix with a plurality of inorganic or synthetic granules bonded or held together by a polymer matrix (*see 9:23-25 which states that the implant may be formed of polymers, ceramics and metals; see table 1 for a listing of*

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biodegradable polymers in the construction of the matrix; see 14:42-59; see figure 27 and 34:4254 "spherical structures or beads/granules bonded together).; and wherein the scaffold comprises use of calcium

However Evans et al. does not specify a region of impermeability with a membrane covering at least a part of the composite structure. Li et al. teaches a selectively permeable membrane/jacket (2:3-5; 3:56-67; 4:3-5; 8:25-31) covering at least a part of the scaffold and being sealed (8:62-67). It would have been obvious to one having ordinary skill in the art to take the device of Evans et al. and attach a selectively impermeable (i.e. one zone of impermeability) membrane to the surface of the scaffold because it would allow for the passage of substance up to a predetermined size and prevent the passage of larger substances.

Claim 76 rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. in view of Li et al. and further in view of Slivka et al. 6,783,712. Evans et al. and Li et al. have been disclosed however do not specify the pore range. Slivka et al. teaches the claimed pore range (see 4:4-8). It would have been obvious to construct the scaffold with pore sizes in the claimed range of 1-500 μm to insure thorough anchoring by of the in-grown tissue into the scaffold and is deemed a design modification.

Allowable Subject Matter

Claims 42-45, 50, 52, and 56. 58, 61, 74, 77, 79 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 78 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZETTE J-J GHERBI whose telephone number is (571)272-4751. The examiner can normally be reached on Maxi-Flex.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SUZETTE J-J GHERBI/
Primary Examiner, Art Unit 3738
15 July 2009